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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,547	01/16/2004	Zongcen Charles Xie	033819-071	7118

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/759,547

Applicant(s)

XIE ET AL.

Examiner

Natalia Levkovich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6 and 20-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6 and 20-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendments and remarks dated 11/04/2005 have been acknowledged by the Examiner and entered. Claims 4, 7-19 and 23 have been canceled and claims 1-3, 5-6, and 20-45 are pending in the instant application for consideration.

### ***Claim Rejections - 35 USC § 112***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. Claims 29-30 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The aforementioned claims recite ethoxylated-2,4,7,9-tetramethyl-5-decyne-4,7-diol having an ethylene oxide content in the range of 40-85%. It is unclear what molecular structure is meant by Applicant. Does ethylene oxide content pertain to the diol or to the block polymer?

### ***Claim Interpretation***

4. As amended, claims still do not positively recite dry immunoassay reagent system. Therefore, it is not considered as a part of the claimed invention and is not accorded any patentable weight.

### ***Claim Rejections - 35 USC § 102***

5. Claims 1-3, 5-6, 20-26 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirai (US 5882935).

With respect to claims 1-3, 5-6 and 20-25, see the appropriate paragraphs of the 06/02/2005 Office Action.

Referring to claims 26 and 36, Hirai teaches a hemolysis system which, as was previously discussed, includes surfactants : “the sample to be analyzed is needed to be subjected to the complete hemolysis so as to fully solubilize the hemoglobin into the solution”. Various types of surfactants can used be for hemolysis: nonionic, ionic, ampholytic [‘zwitterionic’ – Examiner], “to improve reactivity and storage stability” (Col.6, lines 30-35, 45-50). In column 11, lines 20-25, Hirai also teaches that, “to improve the characteristics, such as, coating characteristics, diffusibility of the diffusible material, reactivity and storage stability”, the system “may include various organic or inorganic additives, for example, enzyme activators, coenzymes, surfactants [meaning, more than one surfactant – Ex.], pH buffer reagents, fine particles, antioxidants, etc”.

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Thus, the teaching of Hirai encompasses the combination of surfactants, as recited in claims 26 and 36.

***Claim Rejections - 35 USC § 103***

6. Claims 31-35 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai.

With respect to claims 31 and 41, although Hirai does not teach one of the surfactants to be a polyethylene oxide / polypropylene oxide tri-block polymers, these compositions are commonly employed in the art as surfactants (see, for example paragraph 10 of the instant Office Action). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed polyethylene oxide / polypropylene oxide tri-block polymers as second surfactants in the reagent system of Hirai, in order to modify the system characteristics in a desired manner.

Referring to claims 32-35 and 42-45, although Hirai does not teach the specific contents of the surfactants, as claimed, nevertheless, the Court decided *In Re Boesch* (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art.. The choice of the specific contents of the surfactants is a result effective variable as long as the expected result of modifying characteristics of the system is achieved. It would have been within the skill of the art to modify the system of Hirai, such as to employ the best suitable contents of the surfactants obtained in the result of optimization of a result effective variable.

7. Claims 6 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai in view of Spring (US 5643721).

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See the appropriate paragraphs of the 06/02/2005 Office Action

8. Claims 27 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai in view of Scholl et al. (US 4652517).

Although Hirai does not teach one of the second surfactant to be N-hexadecyl-N,N-dimethyl-3-amino-1-propanesulfonate, this compound is well known in the in the above mentioned capacity (see, for example, claim 2 of the i Scholl reference). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed N-decyl-N,N-dimethyl-3-amino-1-propanesulfonate or its modifications as a surfactant in the reagent system of Hirai, in order to modify the system characteristics by adding a well known compound with predictable properties.

9. Claims 28-30 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirai in view of Scholl et al. (US 4652517), and further in view of Simonnet (US 20020142017).

Although Hirai does not teach one of the second surfactant to be ethoxylated-2,4,7,9-tetramethyl-5-decyne-4,7-diol, this compound is well known in the in the above mentioned capacity (see, for example, [0091] of the Simonnet reference). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed ethoxylated-2,4,7,9-tetramethyl-5-decyne-4,7-diol as a surfactant in the reagent system of Hirai, in order to modify the system characteristics by adding a well known compound with predictable properties.

### ***Response to Arguments***

9. Applicant's arguments dated 08/26/2005 have been fully considered but they are not persuasive and moot in view of the new grounds of rejection.

Applicant argues that Hirai does not employ or recognize the need for the second surfactant improving the stability of the solution. Examiner disagrees. Hirai teaches that, "to improve the characteristics, such as, coating characteristics, diffusibility of the diffusible material, reactivity and storage stability", the system "may include various organic or inorganic additives, for example, enzyme activators, coenzymes, surfactants [meaning, more than one surfactant – Ex.], pH buffer reagents, fine particles, antioxidants, etc". Thus, the teaching of Hirai encompasses the combination of surfactants, as recited in claims 26 and 36.

Applicant argues that Hirai teaches storage stability with surfactant coating on test strip, not in dilution solution. Examiner notes that the second surfactant added for stability to the system of Hirai would be inherently present in the solution during the actual use of the test strip.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Chou et al. (US 5089053) – discloses the use of polyethylene oxide / polypropylene oxide block polymers as second surfactants;

McGregor et al. (US 6066620) – discloses pharmaceutical hemolysis

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compositions having improved stability and resistance due to employing a combination of two surfactants.

Sharma (US 6235239) – discloses a composition for the disinfection of biological fluids which contains an anionic surfactant, at least one non-anionic surfactants and a stabilizer.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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